**PATENT** 

**DOCKET NO.:** TIBO-0029 **Application No.:** 09/836,477

Office Action Dated: April 20, 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Brendan Larder, Stuart Bloor, Kurt Hertogs,

Pascale Alfons Rosa Dehertogh and Rudy

Jean Marc Mortier

**Application No.:** 09/836,477

Filing Date: April 18, 2001

**Group Art Unit:** 1631

Examiner: Lori A. Clow

Confirmation No.: 8810

For: Methods for Measuring Therapy Resistance

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### **DECLARATION PURSUANT TO 37 C.F.R. 1.131**

We, Brendan Larder, Stuart Bloor, Kurt Hertogs, Pascale Alfons Rosa Dehertogh and Rudy Jean Marc Mortier, declare as follows:

- 1. We are the named inventors in the above-identified application.
- 2. We have read the specification and the claims as originally filed in the application and as presented in the pending claims shown in the attached Exhibit A. Each of us contributed to the conception of the invention as defined by one or more of the claims as set forth in Exhibit A.
- 3. Before March 2000, we completed the invention in this country, or in a NAFTA country, or a WTO member country. Our actual reduction to practice of the claimed invention, directly or through persons under our direction and control, before March 2000, is evidenced by the following:
- A. Attached as Exhibit B is a true and accurate copy (except for redaction of dates) of witnessed report, prepared by Kurt Hertogs ("the Hertogs Report"). Hertogs memorializes the claimed invention as shown in Exhibit A. The Hertogs Report at Exhibit B, is dated prior to March 2000.

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B. The Hertogs report discloses in Exhibit B at page 4, ¶1.1, the "System and System Features to be tested" which discloses the steps as claimed in pending claim 1.

- C. The Hertogs report discloses in Exhibit B "VircoGen II, i.e., the prediction of genotypic resistance based on available phenotypic data." (see Exhibit B at page 4, ¶1.1).
- D. The Hertogs report in Exhibit B at page 4,  $\P$ 1.1, describes, in detail, new steps to validate the calls based on phenotypic data. The new steps include:
  - 1. Create Hot Spots from rules, or use a set of predefined Hot Spots (preferred) (see Exhibit B at page 4, ¶1.1).
  - 2. Import a reference set of genotypic and phenotypic data (AV\_Data). The program will identify sequences belonging to each Hot Spot and link them to the Hot Spots (see Exhibit B at page 4, ¶1.1).
  - 3. From the Hot Spots "Special" button, recalculate the Phenotypic Sets. This will link the set of corresponding phenotypes to each Hot Spot (see Exhibit B at page 4,  $\P1.1$ ).
  - 4. For each test sequence, a report is created using the new method to determine genotypic resistance. A set of "Profiles" is automatically calculated for each drug. A profile consists of a set of Hot Spots (either positive or negative). To belong to a profile, a test sequence must obey to all of the positive Hot Spots, and may not belong to any of the negative Hot Spots. The mean and median phenotypic resistance are also calculated for each Profile (see Exhibit B at page 4, ¶1.1).
- E. The Hertogs report discloses in Exhibit B at page 8 examples of drugs used in the method as claimed.
- F. The Hertogs report discloses in Exhibit B at page 8 the following note: "he[sic] phenotypes and sequence data should be imported, the hot spots should be correct and the phenotype set should be calculated before starting the test script."
- G. The Hertogs report discloses in Exhibit B at page 21 various fields in an Excel file which include: sequence identifier; drug (compound tested), fold resistance observed in the antivirogram linked to a sequence; phenotypic call for the real data; and original virtual fold resistance.
- H. The Hertogs report discloses in Exhibit B at page 24 under the header "7. Test Summary Log" the following: "Verify the scoring of genotypic calls in the VircoGen<sup>TM</sup> database (virtual phenotypes)".
- I. The Hertogs report in Exhibit B therefore shows in detail all the steps to be performed to arrive at the result as claimed in Exhibit A.

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4. All statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true. These statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date	Brendan Larder
Date	Stuart Bloor
May Lord Date	Kurt Hertogs
	Pascale Alfons Rosa Dehertogh
Date 27-11AY-2006	Rudy Jean Marc Mortier
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5/6/06	100m
Date	Brendan Larder
Date	Stuart Bloor
Date	Kurt Hertogs
Date	Pascale Alfons Rosa Dehertogh
Date	Rudy Jean Marc Mortier

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Application 110: 07/050,477

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09/06/2006	De De
Date	Stuart Bloor
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